

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 24, 2022

Findings Date: June 24, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Michael J. McKillip

Project ID #: F-12216-22

Facility: Atrium Health Cabarrus

FID #: 943049

County: Cabarrus

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Replace existing fixed PET/CT Scanner

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The Charlotte-Mecklenburg Hospital Authority (CMHA), hereinafter referred to as the applicant or CMHA, does business as Atrium Health and is part of Atrium Health, Inc., a non-profit corporation that operates CMHA and Wake Forest Baptist Medical Center. CMHA operates Atrium Health Cabarrus (AHC), an acute care hospital located in Concord, in Cabarrus County. Atrium Health Cabarrus operates an outpatient imaging center, Atrium Health Cabarrus Imaging (AHCI). In this application, AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2022 SMFP

- acquire any medical equipment for which there is a need determination in the 2022 SMFP
- offer a new institutional health service for which there are any policies in the 2022 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

Patient Origin

On page 365, the 2022 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s **service area** is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET/CT scanner in Cabarrus County which, according to Appendix A on page 371 is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical patient origin for calendar year (CY) 2021 for AHCI’s existing PET/CT scanner at AHCI, from page 37 of the application:

Historical Patient Origin, AHCI CY 2021

COUNTY	# OF PATIENTS	% OF TOTAL
Cabarrus	638	59.8%
Rowan	166	15.6%
Stanly	93	8.7%
Mecklenburg	88	8.2%
Iredell	26	2.4%
Other*	56	5.2%
Total	1,067	100.0%

Source: Application page 37

*Applicant states “other” includes Alleghany, Anson, Caldwell, Catawba, Cleveland, Cumberland, Davidson, Gaston, Guilford, Johnston, Lincoln, Montgomery, Rutherford, Scotland and Union counties and other states.

The following table illustrates historical patient origin for calendar year (CY) 2021 for AHC’s entire campus, from page 38 of the application:

Historical Patient Origin, AHC Entire Campus CY 2021

COUNTY	# OF PATIENTS	% OF TOTAL
Cabarrus	198,294	62.6%
Rowan	48,130	15.2%
Mecklenburg	33,404	10.5%
Stanly	18,575	5.9%
Iredell	4,540	1.4%
Other*	13,829	4.4%
Total	316,772	100.0%

Source: Application page 38

*Applicant defines “other” on page 38.

The following table illustrates projected patient origin for AHCI PET services for the first three full fiscal years (FY) of operation, CYs 2024-2026, from page 39 of the application:

AHCI Projected Patient Origin

COUNTY	1 ST FULL FY (CY 2024)		2 ND FULL FY (CY 2025)		3 RD FULL FY (CY 2026)	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Cabarrus	675	59.8%	688	59.8%	701	59.8%
Rowan	176	15.6%	179	15.6%	182	15.6%
Stanly	98	8.7%	100	8.7%	102	8.7%
Mecklenburg	93	8.2%	95	8.2%	97	8.2%
Iredell	28	2.4%	28	2.4%	29	2.4%
Other*	59	5.2%	60	5.2%	62	5.2%
Total	1,129	100.0%	1,150	100.0%	1,172	100.0%

Source: Application page 39

*Applicant states “other” includes Alleghany, Anson, Caldwell, Catawba, Cleveland, Cumberland, Davidson, Gaston, Guilford, Johnston, Lincoln, Montgomery, Rutherford, Scotland and Union counties and other states.

In Section C, page 39 and Form C, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on the applicant’s historical experience in providing PET services on its existing PET/CT scanner.

Analysis of Need

In Section C, pages 41-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states the proposed replacement PET/CT scanner need is qualitative (page 41).
- Need in Cabarrus County – citing data from the North Carolina Office of State Budget and Management (OSBM), the applicant states Cabarrus County is the third fastest growing county in North Carolina. The applicant states that, from 2011 to 2021, the

county population increased by 21.6% and is projected to increase by a compound annual growth rate (CAGR) of 2.0%, faster than the states as a whole, as shown in the following table from page 42:

Top Five Fastest Growing Counties in NC 2011-2021

FISCAL YEAR	2011	2021	POPULATION CHANGE	% GROWTH	CAGR
Brunswick	110,157	150,889	40,732	37.0%	3.2%
Johnston	172,108	216,670	44,562	25.9%	2.3%
Cabarrus	180,719	219,830	39,111	21.6%	2.0%
Chatham	64,403	78,199	13,796	21.4%	2.0%
Mecklenburg	940,151	1,138,138	197,987	21.1%	1.9%
North Carolina	9,656,099	10,658,717	1,002,618	10.4%	1.0%

The applicant states the same growth is projected over the next ten years and beyond, according to the NC OSBM. In addition, the applicant states the cancer rate in Cabarrus County has increased and will continue to do so as the population increases. The replacement PET/CT scanner with updated technology is needed to address the population growth and increase in cancer in the service area (pages 42-43).

- Existing PET/CT scanner outdated – The applicant states the existing fixed PET/CT scanner proposed to be replaced is 18 years old and is the oldest scanner in CMHA’s fleet. The applicant states image quality is outdated and thus diminishing. Additionally, the cost of repair is high because parts are difficult to find for the older unit. In addition to difficulty in finding parts for an older scanner, the down time for repairs can be several days, which negatively impacts patients, because AHCI is the only provider of PET services in Cabarrus County. Cancer patients are more profoundly impacted by service downtime (page 43).
- Newer technology will improve patient outcomes – the applicant states a new PET/CT scanner will improve patient care because image quality will improve, new technology produces higher quality images, and the scans will take less time and be more efficient, thus accommodating those patients who have mobility issues. The applicant states the proposed new PET/CT scanner will allow radiologists to provide efficient and accurate diagnoses for their patients at a lower radiation dose as well (page 43).

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization for the existing and proposed replacement fixed PET/CT scanner through the first three operating years of the proposed project (CY 2024-CY 2026) as summarized in the following tables:

Historical and Interim Utilization, AHCI PET Services

	PRIOR FULL FY (CY 2021)	INTERIM FULL FY (CY 2022)
Fixed PET scanner	1	1
Number of Procedures	1,067	1,087

Projected Utilization, AHCI PET Services

	INTERIM FULL FY (FY 2024)	1 ST FULL FY (CY 2024)	2 ND FULL FY (CY 2025)	3 RD FULL FY (CY 2026)
Fixed PET scanner	1	1	1	1
Number of Procedures	1,108	1,129	1,150	1,172

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, which is summarized as follows:

Historical utilization – The applicant provides historical utilization on its existing PET/CT scanner from FFY 2019 to FFY 2021 and calculates a compound annual growth rate (CAGR) for that time, as shown in the following table:

AHCI Historical PET Utilization and CAGR, CY 2019-CY 2021

	CY 2019	CY 2020	CY 2021	CAGR 2019-2020	CAGR 2020-2021
PET/CT Procedures	1,101	1,133	1,067	2.9%	-1.6%

As shown above, the applicant reports that PET/CT scanner utilization increased by 2.9% from FY 2019-FY 2020. Thereafter, the applicant states the COVID-19 pandemic and the Stay at Home Order issued by the Governor negatively impacted health care providers across the state, including CMHA. The applicant states it experienced “*significant volume declines*” at the onset of the pandemic and on into CY 2021. The applicant states most recent volumes indicate that utilization is returning to normal at AHCI.

Population growth in Cabarrus County – the applicant states the population growth in the county is driving increased utilization for PET/CT services and other oncology services. The population of Cabarrus County is projected to increase by a CAGR of 1.9% from 2021-2026, according to data provided by the applicant from ERSI, an international supplier of geographic information system software, web GIS and geodatabase management applications.¹

The applicant projects utilization of the replacement PET/CT scanner by applying the 1.9% population growth CAGR as shown in the following table:

¹ <https://www.esri.com/en-us/home>

AHCI Projected PET Utilization, CY 2021-CY 2026

	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CAGR
PET/CT Procedures	1,067	1,087	1,108	1,129	1,150	1,172	1.9%

The applicant states that by applying the historical population growth CAGR to future PET/CT utilization, the scanner will perform only 71 more procedures in the third project year than in CY 2020.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections are supported by the historical utilization of the existing PET/CT scanner currently operating at AHCI.
- The applicant’s utilization projections are supported population growth projections in the service area.
- The applicant’s utilization projections are conservative, given the historical utilization rate of 2.9% and the projected utilization rate of 1.9%, consistent with population growth projections.

Access by Medically Underserved Groups

In Section C, page 50, the applicant states AHCI serves all persons in need of medical care regardless of race, color, religion, national origin, sex, age, disability or source of payment.

On page 51, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE 3 RD FULL FY
Low Income Persons	*
Racial and Ethnic Minorities	22.3%
Women	62.3%
Persons With Disabilities	*
Persons 65 and older	34.3%
Medicare Beneficiaries	40.8%
Medicaid Recipients	15.6%

Numbers may not sum due to rounding.

*The applicant states CMHA does not maintain data that accounts for low income persons or persons with disabilities.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents historical and projected access to AHCI’s PET services for all residents of the service area, including underserved groups.

- The applicant provides its projected payor mix, which includes underserved groups, for the first three years of operation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

In Section E, page 54, the applicant describes the one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- Maintain the status quo – The applicant states this is not an effective alternative, because this application proposes to replace an existing, well-utilized, outdated PET/CT scanner at the AHCI location. The applicant states status quo is affecting the quality of patient care, since the existing scanner is so old and the image quality is poor.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The proposal will meet the applicant's need for a replacement fixed PET/CT scanner at AHCI to serve its patients.
- The applicant provides reasonable and supported information to explain why it believes the proposed project is the most effective alternative to meet the need for a PET scanner in HSA III.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Charlotte-Mecklenburg Hospital Authority (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at Atrium Health Cabarrus Imaging, for a total of no more than one fixed PET/CT scanner at Atrium Health Cabarrus Imaging.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on November 1, 2022.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

5. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
 6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below:

Construction Costs	\$349,100
Medical Equipment	\$2,024,700
Miscellaneous Costs	\$278,700
Total	\$2,652,500

Source: Application Section Q

In Section F, page 65, the applicant states there will be no start-up costs or initial operating expenses since the hospital is operational.

In Section Q, page 4 following Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases its costs on similar projects it has undertaken in the past.
- The applicant bases architect fees and equipment costs on similar projects and vendor quotes.
- The applicant provides a vendor quote in Exhibit C.1-2 for the proposed equipment.
- The applicant provides a certified cost estimate from its architect verifying the proposed capital cost of the project in Exhibit F.1.

Availability of Funds

In Section F, page 62, the applicant states the capital cost will be funded as shown in the table below.

TYPE	CMHA	TOTAL
Loans	\$0	\$0
Cash and Cash Equivalents	\$2,652,500	\$2,652,500
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,652,500	\$2,652,500

* OE = Owner's Equity

In Exhibit F.2-1 contains a letter dated April 18, 2022 from the Executive Vice President and Chief Financial Officer for CMHA, that documents the availability of sufficient accumulated reserves for the capital needs of the proposed project. Exhibit F.2-2 contains the audited financial statements of CMHA that show that as of December 31, 2020, CMHA had \$906,623,000 in cash and cash equivalents and \$13 billion in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer for CMHA that documents the availability of sufficient funds to finance the proposed project.
- The letter from the CFO also commits the funds to the development of the proposed project.
- Exhibit F.2-2 contains a copy of CMHA's balance sheet as of December 31, 2020, showing adequate funds and revenue necessary to cover the capital costs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below:

Projected Revenue, First Three Full Fiscal Years PET Services

	INTERIM YEAR CY 2023	1ST FULL FY CY 2024	2ND FULL FY CY 2025	3RD FULL FY CY 2026
Total Procedures	1,108	1,129	1,150	1,172
Total Gross Revenues (Charges)	\$7,843,251	\$8,232,063	\$8,640,148	\$9,068,464
Total Net Revenue	\$2,140,002	\$2,246,088	\$2,357,432	\$2,474,297
Average Net Revenue per Procedure	\$1,931	\$1,989	\$2,050	\$2,111
Total Operating Expenses (Costs)	\$931,145	\$982,176	\$1,010,945	\$1,041,004
Average Operating Expense per Procedure	\$840	\$870	\$879	\$888
Net Income	\$1,208,857	\$1,263,912	\$1,346,487	\$1,433,293

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 9-10. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases its projections on its historical experience.
- The applicant accounts for and explains the basis for projected operating expenses such as salaries, supplies, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

On page 365, the 2022 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s **service area** is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET/CT scanner in Cabarrus County which, according to Appendix A on page 371 is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA III, and the number of procedures for each PET scanner in 2019-2020 as found in Table 17F-1 on page 367 of the 2022 SMFP:

TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Atrium Health Cabarrus	1	1,135
Fixed	Atrium Health Union	1	589
Fixed	Carolinas Medical Center	2	4,287
Fixed	CaroMont Regional Medical Center	1	843
Fixed	Iredell Memorial Hospital	1	534
Fixed	Novant Health Presbyterian Medical Center	1	2,039

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET scanners services in HSA III. The applicant states:

“Atrium Health Cabarrus Imaging is proposing to replace its existing fixed PET/CT scanner so there will be no addition to the HSA III inventory of PET scanners. Further, Atrium Health Cabarrus Imaging is the only facility that offers PET services in Cabarrus County, as well as the only PET facility north of Charlotte along the I-85 corridor.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposed PET/CT scanner is a replacement PET/CT scanner to be located at Atrium Health Cabarrus Imaging.
- The applicant adequately demonstrates that the proposed fixed PET/CT scanner is needed in addition to the existing or approved PET scanners in HSA VI.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Form H, Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed PET services for the first three full fiscal years (FY) of operation, as illustrated in the following table:

POSITION	1 ST FULL FY (CY 2024)	2 ND FULL FY (CY 2025)	3 RD FULL FY (CY 2026)
Full Time Tech	1.0	1.0	1.0
PRN Tech	0.1	0.1	0.1
Total	1.0	1.0	1.0

The assumptions and methodology used to project staffing for the PET/CT scanner services are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 74 and 75, respectively, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

Ancillary and Support Services

In Section I, page 76 the applicant identifies the necessary ancillary and support services for the proposed services. On page 77, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services and states the same providers will be available for the proposed PET services.
- The applicant explains how AHCI currently provides similar ancillary and support services on its existing PET/CT scanner and describes how those same relationships will be in place to provide ancillary and support services on the proposed replacement PET/CT scanner.

Coordination

In Section I, page 77 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides PET services in the service area and has established relationships with local healthcare providers, which will be in place in the proposed program as well.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

In Section K, page 80, the applicant states that the proposed replacement PET/CT scanner will require minor renovation of 839 square feet of existing space within the area currently housing the existing PET/CT scanner.

On page 81, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the project will be developed in existing space in the same area currently occupied by the existing PET/CT scanner, requiring minimal renovation due to the removal of the existing PET/CT scanner and minimal changes to the slab to accommodate the replacement PET/CT scanner.
- The applicant states the design and means of the proposed renovation were developed to minimize the cost of the project and involve reusing existing fixtures where possible.
- The applicant provides a cost certification letter from its architect in Exhibit F-1.
- The applicant provides line drawings in Exhibit C-1.1.

On page 81, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the project will be funded with accumulated reserves previously set aside by the applicant, which allows the applicant to replace the existing, outdated PET/CT scanner while avoiding increased charges to the patients who will be served.

On page 81 and in Section B, pages 27-28 the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 84, the applicant provides the historical payor mix during fiscal year 2020 for the existing PET services, as shown in the table below:

PAYOR SOURCE	AHCI PET SCANS AS % OF TOTAL
Self-pay	7.6%
Medicare*	40.8%
Medicaid*	15.6%
Insurance*	33.5%
Other	2.5%
Total	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

On page 84, the applicant states internal data does not include charity care as a payor source, and workers compensation and TriCare are included in the “other” category.

In Section L.1(b), page 85, the applicant provides the following comparison for the last full FY before application submission:

ATRIUM HEALTH CABARRUS	PERCENTAGE OF TOTAL PATIENTS SERVED	PERCENTAGE OF POPULATION OF CABARRUS COUNTY
Female	62.3%	51.2%
Male	37.6%	48.8%
Unknown	0.1%	0.0%
64 and Younger	65.7%	86.6%
65 and Older	34.3%	13.4%
American Indian	0.4%	0.7%
Asian	0.9%	4.7%
Black or African-American	20.1%	19.6%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	65.6%	72.4%
Other Race	0.8%	2.5%
Declined / Unavailable	12.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 86, the applicant states it is under no obligation to provide uncompensated care, community service or access by minorities and handicapped persons. However, the applicant states it provides care to all patients in need of medical care, regardless of race, color, religion, national origin, sex, age, disability or source of payment.

In Section L, page 87, the applicant states that during the 18 months immediately preceding the application deadline, no civil rights equal access complaints have been filed against any affiliated entity of Atrium Health Cabarrus.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3, page 87, the applicant provides the projected payor mix for the third operating year (CY 2026) for the proposed project, as shown in the table below:

PAYOR SOURCE	AHCI PET SCANS AS % OF TOTAL
Self-pay	7.6%
Medicare*	40.8%
Medicaid*	15.6%
Insurance*	33.5%
Other	2.5%
Total	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

On page 87, the applicant states internal data does not include charity care as a payor source, and workers compensation and TriCare are included in the “other” category.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.6% of PET/CT services will be provided to self-pay patients, 40.8% to Medicare patients, and 15.6% to Medicaid patients.

In Section L.3, page 87, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant’s historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 89, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purpose. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently has extensive training relationships with health professional training programs such as Central Piedmont Community College, Queens University of Charlotte and others.
- The applicant states those same programs will be in place following the replacement of the PET/CT scanner.
- The applicant provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

AHC proposes to acquire one fixed PET/CT scanner to replace the existing fixed PET/CT scanner located at AHCI.

On page 365, the 2022 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s **service area** is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET/CT scanner in Cabarrus County which, according to Appendix A on page 371 is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA III, and the number of procedures for each PET scanner in 2019-2020 as found in Table 17F-1 on page 367 of the 2022 SMFP:

TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Atrium Health Cabarrus	1	1,135
Fixed	Atrium Health Union	1	589
Fixed	Carolinas Medical Center	2	4,287
Fixed	CaroMont Regional Medical Center	1	843
Fixed	Iredell Memorial Hospital	1	534
Fixed	Novant Health Presbyterian Medical Center	1	2,039

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

“The proposed project will enhance competition in the service area by promoting cost effectiveness, quality and access to PET services.”

In addition, the applicant proposes to replace an existing, outdated PET/CT scanner, rather than add to the inventory of PET/CT scanners in the service area.

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93, the applicant states:

“The proposed application is indicative of CMHA’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, while also ensuring that it develops the services and capacity to meet the needs of the population it serves. ... the fixed PET/CT scanner at Atrium Health Cabarrus Imaging is 18 years old – the oldest scanner in CMHA’s fleet by a wide margin, which results I the need for more frequent repairs and down-time.”

See also Sections B, C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality and access by medically underserved groups, in Section N, page 93, the applicant states:

“CMHA is known for providing high quality services and expects the proposed project to improve the quality of its PET services in Cabarrus County while bolstering its high quality reputation.”

See also Sections B, C, L and O of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant lists a total of 12 of this type of facility located in North Carolina.

In Section O, page 98 the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care occurred on November 12, 2020 in Atrium Health Cleveland resulting in a finding of Immediate Jeopardy. The applicant states that by letter dated December 11, 2020 the issue was corrected and the Immediate Jeopardy was removed. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, one incident related to quality of care occurred in the hospital. Those files confirm that the incident was corrected and the hospital was back in compliance as of December 11, 2020. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all DUH facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to replace an existing PET/CT scanner at Atrium Health Cabarrus Imaging. The Criteria and Standards for Positron Emission Tomography Scanners, which are promulgated in 10A NCAC 14C .3700 are not applicable to reviews for replacement equipment.